

Package was filed within the governing filing deadline. All required documentation that has already been submitted with respect to the deceased person will be considered part of the amended Request Package, and the representative of the estate is not required to resubmit such documentation.

Subpart F—Required Documentation To Be Deemed Eligible

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

§ 102.50 Medical records necessary to establish that a covered injury was sustained.

(a) In order to establish that a smallpox vaccine recipient or vaccinia contact sustained a covered injury, a requester must submit the following medical records:

(1) All physician, clinic, or hospital outpatient medical records documenting medical visits, consultations, and test results that occurred on or after the date of the smallpox vaccination or exposure to vaccinia; and

(2) All inpatient hospital medical records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all progress notes, and all test results that occurred on or after the date of the smallpox vaccination or exposure to vaccinia.

(b) A requester may submit additional medical documentation that he or she believes will support the Request Package. Although generally not required if a Table injury was sustained, a requester may need to introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure (including the smallpox vaccine) or vaccinia contracted through accidental vaccinia inoculation.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the requester after he or she has made reasonable efforts to obtain the records, the requester must submit a statement describing the reasons for the records' unavailability and

the efforts he or she has taken to obtain the records. The Secretary has the discretion to accept such a statement in place of the unavailable medical records. In this circumstance, the Secretary may require an authorization from the requester (or his or her representative) to try to obtain the records on his or her behalf.

(d) In certain circumstances, the Secretary may require additional medical records to make a determination that a covered injury was sustained (e.g., medical records prior to the date of vaccination or accidental vaccinia exposure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination (e.g., records that are duplicative of other records submitted). If the Program requests additional medical records (or information) from a requester's health care practitioner, then the requester may use a release form in order to have the medical records sent directly to the Program.

§ 102.51 Documentation a smallpox vaccine recipient must submit to be deemed eligible by the Secretary.

(a) A smallpox vaccine recipient must submit the following documentation in order to be deemed eligible by the Secretary:

(1) A completed (to the fullest extent possible) and signed Request Form.

(2) Documentation demonstrating that the requester:

(i) Is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties who has volunteered and been selected to be a member of a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified within or outside of the United States and that the requester is or will be functioning in a role identified in a smallpox emergency response plan; and

(ii) Was administered a smallpox vaccine pursuant to an approved smallpox emergency response plan during the effective period of the Declaration.